## REMARKS

### Claim Amendments

Claims 130 and 135 are amended to conform to the antecedent language in claim 122.

Claim 134 is amended to more particularly recite that retraction cavity of the plunger is vented behind the plunger seal element.

Claim 135 is amended to depend from claim 122 through claim 145 instead of directly from claim 122.

### Claim Rejections Under 35 U.S.C. § 102

**Tsao '018:**

**Claim 96** is rejected under 35 U.S.C. §102(b) as anticipated by U.S. 5,084,018 to Tsao. Applicant respectfully traverses this rejection. Claim 96 recites inter alia:

> . . . the body further comprising a rigid stop surface that is contacted directly by the forward facing surface of the plunger seal and stops forward movement of the plunger inside the body following release of the retractable needle.

Tsao ('018) fails to disclose this recited structure.

Examiner refers specifically to FIG. 4 of Tsao ('018) at page 2, par. 3, of the Office Action. Referring to FIG. 4, which is also reproduced for convenience and labeled as Exhibit A to this Response, it is clear that any further forward movement of plunger (50) relative to barrel (12) is prevented by facing and abutting contact between thumb rest (57) and the rearwardly facing surfaces of barrel (12), and not by direct contact between the forward facing surface of the plunger seal (stopper 58) and any part of the body as recited in Claim 96.

FIG. 4 of Tsao ('018) does, however, disclose the position of the plunger relative to the barrel following release of the retractable needle. Referring to FIG. 4 and Exhibit A, the forwardly facing surface of the plunger seal (stopper 58) is clearly identified, and does not directly contact any rigid stop surface of the body. Instead, the forwardly facing surface of the plunger seal contacts only the rearwardly facing surface of sliding base (20), which is also clearly identified in Exhibit A. Neither the rearwardly extending portion of needle extender (19) nor limiting flange (26) disclosed by Tsao ('018) "is contacted directly by the forward facing surface of the plunger seal and stops forward movement of the plunger inside the body following release of the retractable needle" as recited in Applicant's claim 96. As seen in FIG. 4 and in Exhibit A, following release of the retractable needle, limiting flange (26) of Tsao ('018) is in fact disposed inside the forwardly extending portion of a ring groove in the side of the plunger seal (stopper 58), where it would not stop "forward movement of the plunger inside the body" even if thumb rest (57) was not abutting against the rearwardly facing surface of barrel (12).

Tsao ('018) addresses the function of limiting flange (26) only in relation to FIGS. 1 and 2 (at column 1, last line through column 2, line 8) as follows:

> A limiting flange (26) is provided at an appropriate location on the inner wall of the front end of the barrel (12) to prevent the sliding base (20) from downward displacement so that the locking tip (34) and the sliding base (20) are positioned at a ready position. The sliding base (20) has a ring groove (28) at a lateral side to engage with the limiting flange (26) at the inner wall of the barrel (12) to prevent its downward displacement.

In the quoted language, "downward" is understood to mean "rearward" because in FIGS. 1 and 2 of Tsao ('018) limiting flange (26) is disposed at the forwardly extending end of ring groove (28). There is no disclosure in Tsao ('018) teaching or suggesting that a function of limiting

flange (26) is to stop "forward movement of the plunger inside the body following release of the retractable needle" as recited in claim 96.

Because Tsao ('018) fails to disclose the recited element of Applicant's claim 96, Tsao ('018) cannot anticipate the subject matter recited in Applicant's claim 96, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Dysarz '369**:

Claims 113-115 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. 5,180,369 to Dysarz. Applicant respectfully traverses this rejection.

**Claim 113** recites:

> A syringe assembly having a retractable needle and designed for one-time use, comprising: a hollow syringe body having a barrel further comprising a front end portion supporting a needle retraction mechanism comprising a needle holder and a compression spring having a forward end, the front end portion having a small diameter open end disposed forwardly of any larger diameter section of the barrel, wherein any forward movement of the needle holder relative to the barrel is limited by an annular shoulder disposed adjacent to and defining the small diameter open end at a narrowest part of the barrel, the annular shoulder being adjacent to the forward end of the spring.

Dysarz ('369) fails to disclose all the elements recited in claim 113.

Examiner refers specifically to FIG. 1 of Dysarz ('369) at page 2, par. 4, of the Office Action, stating that Dysarz teaches "a hollow body (1), a needle holder (3, 21), compression spring (6), and annular shoulder (5) with forward end (19)." In applying Dysarz ('369) to claim 113, Examiner either disregards or does not address the fact that the reference fails to disclose either (1) an annular shoulder adjacent to the forward end of the spring that defines the small diameter open end of the front portion of the barrel at a narrowest part of the barrel; or (2) an

annular shoulder that defines the small diameter open end of the front portion of the barrel and is adjacent to the forward end of the spring, where said annular shoulder limits any forward movement of the needle holder relative to the barrel.

In Dysarz ('369), the "narrowest part of the barrel" is snap flange (19) and "the small diameter open end" of the front portion of the barrel at the "narrowest part of the barrel" is that portion of the barrel disposed inwardly of snap flange (19), as is disclosed in FIG. 1 and at column 5, lines 16-19, of the patent and in Exhibit B to this Response, which is FIG. 1 of the cited patent as reproduced and labeled for easier reference.

In Dysarz ('369), forward movement of the needle holder relative to the barrel is limited by facing and abutting contact between the underside of slidable piston flange (23) and the rearwardly extending "second" end of guide tube (5). See, for example, the disclosure at column 3, lines 35-37, of Dysarz ('369) and Exhibit B. The second end of guide tube (5) of Dysarz ('369) is disposed adjacent to the rear end, not the forward end, of the spring as is recited in claim 113.

Because Dysarz ('369) fails to disclose all the recited elements of Applicant's claim 113, Dysarz ('369) cannot anticipate the subject matter recited in Applicant's claim 113, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 114** recites:

> The syringe assembly of claim 113 wherein the needle holder abuts the annular shoulder.

For reasons discussed above in relation to claim 113, Dysarz ('369) fails to disclose all the elements of claim 114 that are recited in claim 113. In Dysarz ('369) the needle holder appears to be needle cannula foundation (21) that is threaded into slidable piston (3) disposed inside

guide tube (5). Dysarz ('369) also fails to disclose an annular shoulder as recited in claim 113 that is abutted by the needle holder as recited in claim 114.

Because Dysarz ('369) fails to disclose all the recited elements of Applicant's claim 114, Dysarz ('369) cannot anticipate the subject matter recited in Applicant's claim 114, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 115** recites:

> The syringe assembly of claim 114 wherein a portion of the needle holder extends forwardly of any portion of the barrel.

For reasons discussed above in relation to claim 113, Dysarz ('369) fails to disclose all the elements of claim 115 that are recited in claim 113. Because Dysarz ('369) fails to disclose all the recited elements of Applicant's claim 115, Dysarz ('369) cannot anticipate the subject matter recited in Applicant's claim 115, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 116** recites:

> The syringe assembly of claim 113, the hollow syringe body further comprising a back end portion having at least one radially extending member having a front side and a back side, the front side providing finger grips for the syringe body, and a collar comprising an open back end, the collar extending rearwardly of the back side of the at least one radially extending member and longitudinally separating the back side of the at least one radially extending member from the open back end; and
>
> a plunger having a front end portion insertable into the barrel and slidably engageable with the inside diameter of the barrel in front of the at least one radially extending member, the plunger further comprising a retraction cavity adapted to receive a portion of the needle retraction mechanism following retraction of the needle and a plunger end cap disposed rearwardly of the retraction cavity, the plunger end cap being receivable into close proximity with the collar following retraction.

For reasons discussed above in relation to claim 113, Dysarz ('369) fails to disclose the elements of claim 116 that are recited in claim 113.

In applying Dysarz ('369) to claim 116, Examiner either disregards or does not address the fact that the reference fails to disclose "a collar comprising an open back end, the collar extending rearwardly of the back side of the at least one radially extending member and longitudinally separating the back side of the at least one radially extending member from the open back end" as recited in claim 116.

Dysarz ('369) also fails to disclose a "plunger end cap being receivable into close proximity with the collar following retraction" as recited in claim 116.

Because Dysarz ('369) fails to disclose all the recited elements of Applicant's claim 116, Dysarz ('369) cannot anticipate the subject matter recited in Applicant's claim 116, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Botich ('034):**

Claims 122-125, 128-141 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. 4,994,034 to Botich et al. Applicant respectfully traverses this rejection.

**Claim 122** recites:

> A syringe assembly having a retractable needle that is rendered unusable after a single injection of fluid into a patient, the assembly comprising:
>
> a hollow syringe body comprising a barrel and having a front end portion and a back end portion, the back end portion further comprising at least one radially extending member providing finger grips for the syringe body;
>
> a retraction mechanism disposed in the front end portion, the retraction mechanism further comprising a needle holder having a head portion, an elongated needle holding portion, and a longitudinally extending fluid

> passageway through the head portion and the elongated needle holding portion, the head portion further comprising an inner head, a continuous retainer member surrounding the inner head, and a bridging portion disposed between the continuous retainer member and the inner head, wherein said bridging portion couples the continuous retainer member and the inner head to form a fluid seal between the fluid passageway and the barrel prior to retraction, and a compressed retraction spring surrounding at least part of the elongated needle holding portion and biasing the inner head toward the back end portion prior to retraction;
>
> a retractable needle extending into the front end portion of the body through an opening in the front end portion of the body, the retractable needle being held in fixed relation to the elongated needle holding portion of the needle holder and in fluid communication with the longitudinally extending fluid passageway through the head portion and the needle holding portion;
>
> a plunger reciprocally disposed inside the barrel and forming a variable chamber between the plunger and the needle holder prior to and during injection, the plunger being receivable into the barrel through the back end portion of the body and comprising an outer wall, a retraction cavity disposed inwardly of the outer wall, a plunger seal element providing sliding, sealed engagement between the plunger and the barrel and preventing fluid leakage between the plunger and the barrel, the plunger seal element being restrained from sliding longitudinally along the outer wall of the plunger, and a back end with an end cap having an outer periphery; and
>
> a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction;
>
> wherein the continuous retainer member is releasable from the inner head of the needle holder when the plunger is further depressed inside the barrel following injection.

Botich ('034) fails to disclose all the elements recited in claim 122.

Examiner refers specifically to FIGS. 4-5 of Botich ('034) at page 3, par. 5, of the Office Action, stating: "Botich teaches a needle holder (11/13), retainer member (21), spring (15), needle (17), plunger (59), seal (61), plunger tip (65) and barrier (57)." Applicant respectfully controverts Examiner's implied assertion that spring housing (21) of Botich ('034) constitutes the "continuous retainer member" of the "head portion" of the "needle holder" as recited in Applicant's claim 122. It does not. Botich ('034) states at column 6, lines 36-40:

> A cylindrical spring housing 21 includes a plurality of radial spaced resilient fingers 23 which include inwardly engaging an[d] inferiorally positioned hooks 25 on the posterior end 27 of the spring housing 21.

In the device disclosed by Botich ('034), the resilient fingers (23) that retain needle holder (11/13) against the rearwardly directed biasing force exerted by spring (15) against the forwardly facing annular surface of enlarged lip (13) of holder (11) are radially spaced and are not "a continuous retainer member surrounding the inner head" of the needle holder as recited in rejected claim 122.

Applicant also respectfully controverts Examiner's implication that "barrier (57)" of Botich ('034) constitutes "a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction" as recited in Applicant's claim 122. It does not.

First, there is not a lead line associated with reference numeral 57 in FIGS. 4 and 5 of Botich ('034), to which Examiner refers. Applicant refers instead to FIGS. 2 and 3 of Botich ('034), where reference numeral "57" does have lead lines, and to the following disclosure appearing at column 7, lines 14-18, of Botich ('034):

> The first tapered inner wall 57 within the tapered nose 53 of the syringe barrel 55 provides sealing engagement between the spring housing 21 and the syringe barrel 55, due to the tight fit of the O-ring 39 between the spring housing 21 and the first tapered inner wall 57.

Second, in the Botich ('034) device as viewed in FIGS. 1 and 2, tapered inner wall (57) is inclined toward the front of the syringe and provides a sealing surface for O-ring (39) as bayonet tabs (47) of spring housing (21) engage the barrel. Tapered inner wall (57) therefore serves as a

barrier to limit rearward motion of spring housing relative to the barrel. By contrast, the "barrier" recited in Applicant's claim 122 limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction.

Thus, the only statement made by Examiner in applying Botich '034 against claim 122 does not support an anticipation rejection.

Furthermore, in applying Botich ('034) to claim 122, Examiner also either disregards or does not address the fact that the reference fails to disclose:

- A "bridging portion" disposed between the continuous retainer member, wherein the bridging portion couples the continuous retainer member and the inner head to form a fluid seal between the passageway and the barrel prior to retraction; and
- A "variable chamber" between the plunger and the needle holder prior to and during injection.

The radially spaced flexible fingers (23) with hooks (25) as disclosed by Botich ('034) do not form a fluid seal between the passageway and the barrel prior to retraction as recited in Applicant's claim 122. In the device of Botich ('034), fluid (i.e., medicine) can flow downwardly between flexible fingers (23) and around spring (15) and needle holder (11/13), thereby wetting spring (15) with fluid, which is undesirable, and also requiring the use of washer (29) to establish a fluid seal around needle (17) between holder (11) and forward end (35) of spring housing (21). O-ring (39) is also required to form a fluid seal between spring housing (21) and barrel (55). By contrast, Applicant's "continuous retainer member" forms a fluid seal against the barrel, thereby eliminating the need for Botich's O-ring (39) and Applicant's

"bridging portion" forms a fluid seal around the inner head of the needle holder, thereby eliminating the need for Botich's washer (29).

Because, under the hydraulic pressure of the advancing plunger during an injection, fluid can flow forwardly and occupy the volume between flexible fingers (23) and around spring (15) until the fluid reaches washer (29), and between spring housing (21) and barrel (55) until the fluid reaches O-ring (39), respectively, in the device disclosed by Botich ('034), the "variable chamber" of Botich ('034) includes the combined volume of those spaces. By contrast, the "variable chamber" of Applicant's device is the volume disposed "between the plunger and the needle holder."

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 122, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 122, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 123** recites:

> The syringe assembly of claim 122 wherein the retraction mechanism is receivable through the back end portion of the barrel.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 123.

In applying Botich ('034) to claim 123, Examiner either disregards or does not address the fact that the reference fails to disclose a syringe assembly "wherein the retraction mechanism is receivable through the back end portion of the barrel" as recited in claim 123. Claim 123, through claim 122, recites that the "retraction mechanism" comprises a "needle holder" and a "compressed retraction spring." Referring to FIG. 3 of Botich ('034), it is seen that needle holder (11/13) and spring (15) are both installed inside spring housing (21) prior to attachment of

spring housing (21) to tapered nose (53) at the front of barrel (55). By contrast, Applicant's claim 123 recites that the retraction mechanism is receivable through the back end portion of the barrel.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 123, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 123, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 124** recites:

> The syringe assembly of claim 122 wherein the plunger carries a tip that protrudes forwardly of the plunger seal element to contact the needle holder and release the retractable needle when the plunger is further depressed inside the barrel following injection.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 124.

Referring to FIG. 2 of Botich ('034), to which Examiner did not refer in applying Botich ('034) to claim 124, when plunger (59) "is further depressed inside the barrel following injection" as recited in claim 124, and assuming that frangible end (65) is the "plunger tip" as asserted by Examiner, frangible end (65) does not "release the retractable needle" as recited in claim 124. Paraphrasing, Botich ('034) states at column 8, lines 11-20, that when frangible end (65) contacts enlarged lip (13) of holder (11) after injection and dissociates from the outwardly tapered shoulders (68) of plunger (59), resilient fingers (23) flex radially and hooks (25) of spring housing 21 "release the enlarged lip 13 of the holder 11 of the injection needle."

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 124, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 124, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 125** recites:

> The syringe assembly of claim 124 wherein the continuous retainer member is released from the inner head of the needle holder by means of a force applied by the tip to the needle holder.

For reasons discussed above in relation to claims 122 and 124, Botich ('034) fails to disclose the elements of claims 122 and 124 that are recited in claim 125. As to the particular recitations of claim 125, Botich ('034) fails to disclose a "continuous retainer member" as recited by Applicant. As to the release action, Botich ('034) discloses that after injection and dissociation of frangible end (65), hooks 25 release the enlarged lip (13) of holder (11).

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 125, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 125, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 128** recites:

> The syringe assembly of claim 122 wherein the barrel is not distorted during retraction.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 128.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 128, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 128, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 129** recites:

> The syringe assembly of claim 122 wherein the barrier is an annular shoulder disposed in the front portion of the barrel.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 129. As to the particular recitations of claim 129, Botich ('034) fails to disclose a "barrier" as recited in claim 122 that is an "annular shoulder" as recited by Applicant. In applying Botich ('034) to reject claim 129, Examiner either disregards or does not address the fact that the reference fails to disclose an "annular shoulder" as recited in Applicant's claim.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 129, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 129, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

As amended herein to conform to the antecedent language recited in claim 122,

**Claim 130** recites:

> The syringe assembly of claim 129 wherein the annular shoulder is disposed adjacent to the opening in the front end portion of the body.

For reasons discussed above in relation to claim 122 and 129, Botich ('034) fails to disclose the elements of claims 122 and 129 that are recited in claim 130. As to the particular recitations of claim 130, Botich ('034) fails to disclose a "barrier" as recited in claim 122 that is an "annular shoulder" as recited in claim 129 that "is disposed adjacent to the opening in the front end portion of the body" as recited by Applicant. In applying Botich ('034) to reject claim 130, Examiner either disregards or does not address the fact that the reference fails to disclose a syringe assembly wherein the "annular shoulder" of claim 129 is disposed adjacent to the opening in the front end portion of the body.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 130, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 130, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 131** recites:

> The syringe assembly of claim 129 wherein the needle holding portion is grounded on the annular shoulder.

For reasons discussed above in relation to claim 122 and 129, Botich ('034) fails to disclose the elements of claims 122 and 129 that are recited in claim 131. As to the particular recitations of claim 131, Botich ('034) fails to disclose grounding of the needle holding portion on the annular shoulder as recited by Applicant. In applying Botich ('034) to reject claim 131, Examiner either disregards or does not address the fact that the reference fails to disclose grounding the needle holding portion on the annular shoulder.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 131, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 131, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 132** recites:

> The syringe assembly of claim 122 wherein the body has a rigid stop surface that is contacted directly by the plunger seal and stops forward movement of the plunger inside the body when the plunger is further depressed inside the body following injection.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 132. Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 132, Botich ('034) cannot anticipate the subject matter recited in

Applicant's claim 132, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 133** recites:

> The syringe assembly of claim 122 wherein the end cap has an opening and a closure is installed in the opening.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 133. As to the particular recitations of claim 133, Botich ('034) fails to disclose an end cap having an opening and a closure installed in the opening as recited by Applicant. In applying Botich ('034) to reject claim 133, Examiner either disregards or does not address the fact that the reference fails to disclose an end cap having an opening and a closure installed in the opening.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 133, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 133, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

As amended herein, **Claim 134** recites:

> The syringe assembly of claim 122 wherein the retraction cavity is vented behind the plunger seal element.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 134. Botich ('034) also fails to disclose a retraction cavity that is vented behind the plunger seal element as recited by Applicant in amended claim 134. In applying Botich ('034) to reject claim 134, Examiner either disregards or does not address the fact that the reference fails to disclose venting as recited by Applicant.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 134, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 134, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

As amended herein, **Claim 135** recites:

> The syringe assembly of claim 134 wherein the retraction cavity is vented between the plunger seal element and the end cap.

For reasons discussed above in relation to claims 122 and 134, Botich ('034) fails to disclose the elements of claims 122 and 134 that are recited in claim 135. Botich ('034) also fails to disclose a retraction cavity that is vented between the plunger seal element and the end cap as recited by Applicant in amended claim 135.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 135, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 135, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 136** recites:

> The syringe assembly of claim 122 wherein the body comprises a one-piece barrel.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 136. Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 136, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 132, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 137** recites:

> The syringe assembly of claim 122 wherein the continuous retainer member is coupled to the inner head with a holding force that exceeds a biasing force exerted on the inner head by the compressed retraction spring.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 137. Botich ('034) also fails to disclose a "continuous retainer member" that "is coupled to the inner head" as recited in claim 137. In applying Botich ('034) to reject claim 137, Examiner either disregards or does not address the fact that the reference fails to disclose a continuous retainer member that is coupled to the inner head as recited by Applicant.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 137, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 137, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 138** recites:

> The syringe assembly of claim 122 wherein a portion of the elongated needle holding portion extends forwardly of the body.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 138. Botich ('034) also fails to disclose a syringe assembly wherein a portion of the elongated needle holding portion extends forwardly of the body as recited in claim 138. In applying Botich ('034) to reject claim 137, Examiner either disregards or does not address the fact that the reference fails to disclose a syringe assembly wherein a portion of the elongated needle holding portion extends forwardly of the body as recited by Applicant. Referring to FIGS. 4 and 5 of Botich ('034), as identified by Examiner, needle holder (11/13) does not extend forwardly of the body.

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 138, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 138, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 139** recites:

> The syringe assembly claim 122 wherein the continuous retaining member has an outside mating surface making a fluid seal with the barrel.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 139. Botich ('034) also fails to disclose a syringe assembly wherein the continuous retaining member has an outside mating surface making a fluid seal with the barrel as recited in claim 139. In applying Botich ('034) to reject claim 139, Examiner either disregards or does not address the fact that the reference fails to disclose a syringe assembly wherein the continuous retaining member has an outside mating surface making a fluid seal with the barrel as recited by Applicant. Referring to FIGS. 4 and 5 of Botich ('034), as identified by Examiner, the flexible fingers (23) and hooks (25) of spring housing (21) that Examiner stated to be "retainer member (21)" are not radially continuous, and do not make a fluid seal with the barrel, thereby necessitating the inclusion of O-ring seal (39) in the device of Botich ('034) .

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 139, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 139, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 140** recites:

> The syringe assembly of claim 122 wherein the body and the elongated needle holder cooperate as a spring guide during compression of the retraction spring.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 140. Botich ('034) also fails to disclose a syringe assembly wherein the body and the elongated needle holder cooperate as a spring guide during compression of the retraction spring as recited in claim 140. In applying Botich ('034) to reject claim 140, Examiner either disregards or does not address the fact that the reference fails to disclose a syringe assembly wherein the body and the elongated needle holder cooperate as a spring guide during compression of the retraction spring as recited by Applicant. FIG. 3 of Botich ('034) discloses spring (15) compressed inside an annulus between spring housing (21) and holder (11) prior to the attachment of spring housing (21) to tapered nose (53) of barrel (55).

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 140, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 140, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim 141** recites:

The syringe assembly of claim 122 wherein the bridging portion is frangible.

For reasons discussed above in relation to claim 122, Botich ('034) fails to disclose the elements of claim 122 that are recited in claim 141. Botich ('034) also fails to disclose a "frangible" bridging portion" as recited in claim 141. In applying Botich ('034) to reject claim 141, Examiner either disregards or does not address the fact that the reference fails to disclose a frangible bridging portion as recited by Applicant. Botich ('034) instead discloses (e.g., at column 8, lines 21-36) resilient, flexible fingers (23).

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 141, Botich ('034) cannot anticipate the subject matter recited in Applicant's claim 141, and the rejection under 35 U.S.C. §102(b) should accordingly be withdrawn.

**Claim Rejections Under 35 U.S.C. §103**

**Dysarz ('369) in view of Mercado ('138)**

**Claim 116** is rejected under 35 U.S.C. §103(a) as being unpatentable over Dysarz ('369) in view of U.S. 5,304,138 to Mercado. Applicant respectfully traverses the rejection and requests that it be withdrawn.

Claim 116 depends from claim 113. Examiner states that Dysarz '369 teaches the syringe as "described" in claim 113. For reasons explained above in relation to claim 113, and restated below, Applicant respectfully controverts Examiner's conclusion that all the elements of the invention as recited in claim 116 through claim 113 are disclosed by Dysarz '369.

Regarding claim 113, Examiner refers specifically to FIG. 1 of Dysarz ('369) at page 2, par. 4, of the Office Action, stating that Dysarz teaches "a hollow body (1), a needle holder (3, 21), compression spring (6), and annular shoulder (5) with forward end (19)." In applying Dysarz ('369) to claim 113, Examiner either disregards or does not address the fact that the reference fails to disclose either (1) an annular shoulder adjacent to the forward end of the spring that defines the small diameter open end of the front portion of the barrel at a narrowest part of the barrel; or (2) an annular shoulder that defines the small diameter open end of the front portion of the barrel and is adjacent to the forward end of the spring, where said annular shoulder limits any forward movement of the needle holder relative to the barrel.

In Dysarz ('369), the "narrowest part of the barrel" is snap flange (19) and "the small diameter open end" of the front portion of the barrel at the "narrowest part of the barrel" is that portion of the barrel disposed inwardly of snap flange (19), as is disclosed in FIG. 1 and at column 5, lines 16-19, of the patent and in Exhibit B to this Response, which is FIG. 1 of the cited patent as reproduced and labeled for easier reference.

In Dysarz ('369), forward movement of the needle holder relative to the barrel is limited by facing and abutting contact between the underside of slidable piston flange (23) and the rearwardly extending "second" end of guide tube (5). See, for example, the disclosure at column 3, lines 35-37, of Dysarz ('369) and Exhibit B. The second end of guide tube (5) of Dysarz ('369) is disposed adjacent to the rear end, not the forward end, of the spring as is recited in claim 113.

The deficiencies in the teachings of Dysarz '369 are not remedied by Mercado ('138), which also fails, *inter alia,* to disclose either (1) an annular shoulder adjacent to the forward end of the spring that defines the small diameter open end of the front portion of the barrel at a narrowest part of the barrel; or (2) an annular shoulder that defines the small diameter open end of the front portion of the barrel and is adjacent to the forward end of the spring, where said annular shoulder limits any forward movement of the needle holder relative to the barrel. In fact, Mercado does not even disclose a spring.

Because Dysarz ('369) and Mercado ('138), even when taken in combination, fail to disclose all the recited elements of Applicant's claim 113, from which claim 116 depends, that combination of references cannot render obvious the invention as a whole as recited in

Applicant's claim 116. The rejection under 35 U.S.C. §103(a) should accordingly be reconsidered and withdrawn.

**Botich ('034) in view of Mercado ('138)**

Claims 126 and 127 are rejected under 35 U.S.C. §103(a) as being unpatentable over Botich ('034) in view of U.S. 5,304,138 to Mercado. Applicant respectfully traverses the rejection and requests that it be withdrawn.

**Claim 126** recites:

> The syringe assembly of claim 122 wherein the body further comprises a collar having an open back end, the collar extending rearwardly behind the at least one radially extending member and longitudinally separating the at least one radially extending member from the open back end, and wherein the outer periphery of the end cap is in close proximity to the back end of the collar following injection and during retraction.

**Claim 127** recites:

> The syringe assembly of claim 126 wherein the end cap is lodged in close confinement with the back end of the collar after retraction.

Claims 126 and 127 depend from claim 122. Examiner states that Botich '034 teaches the syringe as "described" in claim 122. For reasons explained above in relation to claim 122, and restated below, Applicant respectfully controverts Examiner's conclusion that all the elements of the invention as recited in claims 126 and 127 through claim 122 are disclosed by Botich '034.

Regarding claim 122, Examiner refers specifically to FIGS. 4-5 of Botich ('034) at page 3, par. 5, of the Office Action, stating: "Botich teaches a needle holder (11/13), retainer member (21), spring (15), needle (17), plunger (59), seal (61), plunger tip (65) and barrier (57)." Applicant respectfully controverts Examiner's implied assertion that spring housing (21) of

Botich ('034) constitutes the "continuous retainer member" of the "head portion" of the "needle holder" as recited in Applicant's claim 122. It does not. Botich ('034) states at column 6, lines 36-40:

> A cylindrical spring housing 21 includes a plurality of radial spaced resilient fingers 23 which include inwardly engaging an[d] inferiorally positioned hooks 25 on the posterior end 27 of the spring housing 21.

In the device disclosed by Botich ('034), the resilient fingers (23) that retain needle holder (11/13) against the rearwardly directed biasing force exerted by spring (15) against the forwardly facing annular surface of enlarged lip (13) of holder (11) are radially spaced and are not "a continuous retainer member surrounding the inner head" of the needle holder as recited in rejected claim 122.

Applicant also respectfully controverts Examiner's implication that "barrier (57)" of Botich ('034) constitutes "a barrier disposed in the front end portion of the body that limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction" as recited in Applicant's claim 122. It does not.

First, there is not a lead line associated with reference numeral 57 in FIGS. 4 and 5 of Botich ('034), to which Examiner refers. Applicant refers instead to FIGS. 2 and 3 of Botich ('034), where reference numeral "57" does have lead lines, and to the following disclosure appearing at column 7, lines 14-18, of Botich ('034):

> The first tapered inner wall 57 within the tapered nose 53 of the syringe barrel 55 provides sealing engagement between the spring housing 21 and the syringe barrel 55, due to the tight fit of the O-ring 39 between the spring housing 21 and the first tapered inner wall 57.

Second, in the Botich ('034) device as viewed in FIGS. 1 and 2, tapered inner wall (57) is inclined toward the front of the syringe and provides a sealing surface for O-ring (39) as bayonet tabs (47) of spring housing (21) engage the barrel. Tapered inner wall (57) therefore serves as a barrier to limit rearward motion of spring housing relative to the barrel. By contrast, the "barrier" recited in Applicant's claim 122 limits forward motion of the needle holding portion and the retractable needle relative to the body as the plunger is depressed inside the barrel during injection and retraction.

Furthermore, in applying Botich ('034) to claim 122, Examiner also either disregards or does not address the fact that the reference fails to disclose:

- A "bridging portion" disposed between the continuous retainer member, wherein the bridging portion couples the continuous retainer member and the inner head to form a fluid seal between the passageway and the barrel prior to retraction; and
- A "variable chamber" between the plunger and the needle holder prior to and during injection.

The radially spaced flexible fingers (23) with hooks (25) as disclosed by Botich ('034) do not form a fluid seal between the passageway and the barrel prior to retraction as recited in Applicant's claim 122. In the device of Botich ('034), fluid (i.e., medicine) can flow downwardly between flexible fingers (23) and around spring (15) and needle holder (11/13), thereby wetting spring (15) with fluid, which is undesirable, and also requiring the use of washer (29) to establish a fluid seal around needle (17) between holder (11) and forward end (35) of spring housing (21). O-ring (39) is also required to form a fluid seal between spring housing (21) and barrel (55). By contrast, Applicant's "continuous retainer member" forms a fluid seal

against the barrel, thereby eliminating the need for Botich's O-ring (39) and Applicant's "bridging portion" forms a fluid seal around the inner head of the needle holder, thereby eliminating the need for Botich's washer (29).

Because, under the hydraulic pressure of the advancing plunger during an injection, fluid can flow forwardly and occupy the volume between flexible fingers (23) and around spring (15) until the fluid reaches washer (29), and between spring housing (21) and barrel (55) until the fluid reaches O-ring (39), respectively, in the device disclosed by Botich ('034), the "variable chamber" of Botich ('034) includes the combined volume of those spaces. By contrast, the "variable chamber" of Applicant's device is the volume disposed "between the plunger and the needle holder."

Because Botich ('034) fails to disclose all the recited elements of Applicant's claim 122, Botich ('034) cannot be relied upon by Examiner as teaching "the syringe as described in Applicant's claim 122. Furthermore, the deficiencies in the teachings of Botich '034 are not remedied by Mercado ('138), which does not even disclose a retraction mechanism.

Because Botich ('034) and Mercado ('138), even when taken in combination, fail to disclose all the recited elements of Applicant's claim 122, from which claims 126 and 127 depend either directly or indirectly, that combination of references cannot render obvious the invention as a whole as recited in Applicant's claims 126 and 127. The rejection of claims 126 and 127 under 35 U.S.C. §103(a) should accordingly be reconsidered and withdrawn.

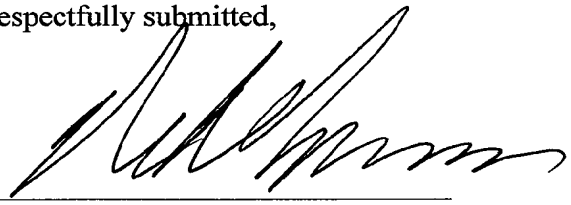
## REQUEST FOR PERSONAL INTERVIEW

Applicant again requests Examiner's consideration in granting Applicant a personal interview prior to issuing another office action if Examiner intends to again reject any of the claims as now presented.

## CONCLUSION

For the reasons discussed above, it is respectfully submitted that all of the claims as now presented are patentable over the prior art. Accordingly, an early reconsideration and allowance of this application is respectfully requested. It is believed that no fees are due in connection with the submission of this paper. If this is incorrect, the Commissioner is hereby authorized to charge any fee due in connection with the filing of this paper to deposit account no. 12-1781 of Locke Lord Bissell & Liddell LLP, formerly Locke Liddell & Sapp PLLC, formerly Locke Liddell & Sapp LLP. (The firm name changed on October 2, 2007, from Locke Liddell & Sapp PLLC to Locke Lord Bissell & Liddell LLP, and the undersigned is unsure at what point the name on the deposit account will be formally changed, although the account number remains the same and the undersigned is authorized to direct the payment of PTO fees using that account.)

Respectfully submitted,



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